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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,561	08/21/1998	JEAN PLOUET	USB95ARCNR	5078

466 7590 10/18/2002

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/18/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/091,561	Plouet et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Sep 18, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*

Claim(s) objected to: *none*

Claim(s) rejected: *25-30 and 32-35*

Claim(s) withdrawn from consideration: *18-24 and 31*

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other:

DETAILED ACTION

Applicant's arguments, filed 3/25/02, have been fully considered but have not been found persuasive. Applicant argues that:
"The specification clearly enables one skilled in the art how to [*sic*] make and use a polyclonal antiserum containing the claimed antibodies, and which is itself a specific embodiment of the claimed invention," and "The claims do not limit the antibody to a polyclonal or a monoclonal antibody. Furthermore, the claimed invention does not require that the antibody be isolated or purified to homogeneity." In this regard it is the Examiner's position that, absent a purification of the claimed antibody, one of skill in the art would not know how to use the antibody of the instant claims. As set forth in the specification, "The advantage of the anti-idiotypic antibodies of the invention being circulating lies in targeting angiogenic endothelial cells with drugs which do not affect quiescent endothelial cells." Thus, if the KDR-specific anti-idiotypic antibodies of the instant claims are not separated from the anti-idiotypic antibodies that would also bind flt, one of skill in the art would not be able to take advantage of their special properties. Accordingly, it remains the Examiner's position that the specification fails to adequately set forth how to make and use the antibodies of the instant claims.

Applicant argues that:
"Applicants would also like to clarify any confusion regarding the unexpected results exhibited by the present invention in that 15 to 20% of immunized animals produce the claimed antibody. Applicants agree that the animals will not elicit 15 to 20% of monoclonal antibodies. Instead, 15-20% of the immunized animals produced the claimed antibody in their polyclonal antiserum." By this argument, it appears that 80 to 85% of the immunized animals produce none of the claimed antibody, indicating that the production of the claimed antibody comprises a relatively rare event. It would be likely then that even the animals that do produce the claimed antibody would produce little of it, and said antibody would be produced in a serum that comprised a much higher concentration of an antibody that binds both KDR and flt. This again demonstrates the need for a purification step that is not disclosed in the specification. While Applicant may argue that "The present invention is not devoted to the purification of antibodies," said purification remains a necessary step in the production of the antibodies of the instant claim.

Applicant argues that:
"One of ordinary skill in the art would readily be able to make monoclonal antibodies according to the invention, given the teaching of the polyclonal antiserum in the present specification." It remains the Examiner's position that the jump from the rabbit polyclonal antiserum comprising a small percentage of the claimed antibody (that would be obtained by the methods disclosed in the instant specification) to a mouse monoclonal antibody (that would actually function for the claimed antibody's intended use) is one that cannot simply be assumed that one of skill in the art could/would make. Note that the specification does not even disclose that the claimed antibody is necessarily monoclonal, said necessity has been established in post-filing actions and declarations. Thus, Applicant's arguments are actually based on the assumption that one of skill in the art would/could determine that the antibody of the instant claims must be monoclonal and then said skilled artisan would/could also produce said antibody. Accordingly, it remains the Examiner's position that the instant specification does not adequately disclose how to make and use the claimed invention.

Applicant argues that:
"The present specification clearly enables one skilled in the art to produce or use Fab fragments of the claimed invention." It remains the Examiner's position that the specification is no more enabling for the production of Fab fragments that bind KDR and not flt than it is for the production of whole antibodies, for the reasons set forth above. Further, it is reiterated that the 9/29/00 declaration of Inventor Plouet, taught that said Fab fragment could not function for the antibody's intended use.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 16, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600